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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,401	01/20/2006	Gary P. Cook	02181.0086U2	1909
23859	7590	08/03/2010	EXAMINER	
Ballard Spahr LLP SUITE 1000 999 PEACHTREE STREET ATLANTA, GA 30309-3915			TRAN, SUSAN T	
			ART UNIT	PAPER NUMBER
			1615	
			MAIL DATE	DELIVERY MODE
			08/03/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/565,401	Applicant(s) COOK, GARY P.	
	Examiner S. TRAN	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 16-36 is/are pending in the application.
- 4a) Of the above claim(s) 1-9 and 19-36 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 10-14 and 16-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>06/04/10</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

This application contains claims 1-9 and 19-36, drawn to an invention nonelected with traverse in the reply filed on 10/15/09. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 103

Claims 10-14, 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Orsolini et al. WO 02/058672 A2, in view of Austin et al. US 4,171,981.

Orsolini teaches a sustained release microparticles formulation comprising a biodegradable polymer, a bioactive agent, a surfactant (organic ion), and an electrolyte (abstract; page 7, lines 6-15; and claims). The microparticles are prepared by providing an organic liquid phase comprising the biodegradable polymer and the bioactive agent, providing an aqueous phase comprising a surfactant, homogenizing the above organic and aqueous phases, and obtaining the microparticles (page 4, lines 17-30; page 6; and examples). Biodegradable polymer includes poly(D-L-lactide-co-glycolide) (page 8, lines 4-16). Surfactant includes anionic, non-ionic, and other surfactants (page 10, lines 8-29). Bioactive agents are disclosed in page 12, which also includes protein, peptide, polypeptide, LHRH, and the like.

Orsolini does not explicitly teach the claimed organic ion.

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Austin teaches a process for the production of a microcapsule comprising the use of a dispersing agent such as naphthalene sulfonic acid (column 6, lines 53-68). Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the microparticles of Orsolini using naphthalene sulfonic acid in view of the teachings of Austin with the expectation of at least similar results. This is because Austin teaches that it is known to use naphthalene sulfonic acid to obtain a microcapsule useful in pharmaceutical art (column 4, lines 22-23), because Austin teaches that naphthalene sulfonic acid is a known anionic compound useful in microcapsule composition, and because Orsolini teaches the desirability for using surfactants including a nonionic compound.

Claim 10-14 and 16-18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Orsolini et al. WO 02/058672 A2, in view of Austin et al. US 4,171,981 and Bodmer et al. US 5,876,761.

Orsolini is relied upon for the reasons above. Orsolini does not expressly teach the claimed bioactive agent.

Bodmer teaches a microparticles composition comprising bioactive agent such as octreotide and salt thereof. See example 4; and claim 1. The composition also comprises pamoate (column 6, lines 37-40; and column 16, lines 5-7).

Thus, it would have been obvious to one of ordinary skill in the art to modify the microparticles composition of Orsolini to include the use of octreotide as a bioactive agent, because Bodmer teaches that octreotide is a useful somatostatin, because

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Bodmer teaches the incorporation of cotreotide in a biodegradable biocompatible polymeric carrier is known in the art (column 11, lines 42-49), and because Orsolini teaches the desirability for using somatostatin in a microparticles composition.

Response to Arguments

Applicant's arguments filed 05/24/10 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's Amendment filed 05/24/10 deleting "pamoate" and "cholate" from the Markush Group of organic ion, necessitated the new ground of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606.

The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/
Primary Examiner, Art Unit 1615